

NO. 22-1399

In The
United States Court Of Appeals
For The Fourth Circuit

JUDITH A. SHEARS; GARY F. SHEARS, JR.,
Plaintiffs – Appellants,

v.

ETHICON, INC.; JOHNSON & JOHNSON,
Defendants – Appellees.

**ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

BRIEF OF APPELLANTS

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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No. 22-1399 Caption: Shears, et al. v. Ethicon, Inc., et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

Judith A. Shears; Gary F. Shears, Jr.
(name of party/amicus)

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If yes, identify all parent corporations, including all generations of parent corporations:
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If yes, identify entity and nature of interest:
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If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:
6. Does this case arise out of a bankruptcy proceeding? ☐ YES ☒ NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.
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If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ Jason P. FosterDate: April 27, 2022Counsel for: Appellants

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I. JURISDICTIONAL STATEMENT

A. Basis for the District Court's Subject Matter Jurisdiction

The United States District Court for the Northern District of West Virginia had subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1332(a)(1) (diversity jurisdiction). (JA 49). The Shears sued Johnson & Johnson and Ethicon, Inc. (hereinafter referred to as “Ethicon”). The Shears reside in and are citizens of West Virginia. (JA 48 at 1). Ethicon and Johnson & Johnson are headquartered in and are citizens of New Jersey. (JA 54, 58, 5585).

B. Basis for the Court of Appeals' Jurisdiction

The United States Court of Appeals for the Fourth Circuit has appellate jurisdiction pursuant to 28 U.S.C. §§ 1291 and 1294 which grant appellate review of final decisions of district courts of the United States. Here, the District Court entered final judgment against the Shears on March 17, 2022 following an 8-day jury trial. (JA 7618-7622; 7623-7629).

C. Filing Dates Establishing Timeliness of Appeal

Under Rule 4 of the Federal Appellate Procedure, a notice of appeal in a civil case must be filed within thirty (30) days after entry of the judgment or order appealed from. The District Court entered its Judgement Order from which the Shears appeal on March 17, 2022. (JA 7623-7629). The Shears filed their Notice of Appeal on April 12, 2022. (JA 7630-7632).

D. Assertion that Appeal is from a Final Order

This appeal follows the entry of Final Judgment in favor of Ethicon which disposed of all parties' claims. (JA 7623-7629).

II. STATEMENT OF THE ISSUES

A. Whether the District Court improperly granted Ethicon summary judgment on the Shears' strict product liability design defect claim on the basis that the Shears could not identify an alternative design that eliminated the risk of injury.

B. Whether the District Court improperly granted Ethicon Judgment as a Matter of Law on the Shears' strict product liability design defect claim under the malfunction theory.

C. Whether the District Court improperly instructed the jury on the Shears' negligence-based product liability claim.

III. STATEMENT OF THE CASE**A. Facts Relevant to the Issues Submitted for Review****1. Ethicon's TVT Mesh**

This is a product liability action concerning a surgical medical device known as TVT transvaginal mesh ("TVT"). (JA 50). The TVT is made of synthetic polypropylene "mesh" that is surgically implanted underneath a woman's urethra to treat stress urinary incontinence ("SUI")—a condition in which a woman leaks urine during moments of physical activity that increase abdominal pressure, such as

laughing, sneezing, or coughing. (JA 5585, 5966). Ethicon manufactured, marketed, and sold the TVT. (JA 5585). Ethicon is a wholly owned subsidiary of Defendant Johnson & Johnson. *Id.*

The Shears presented the following evidence to the jury regarding design flaws associated with the TVT: (1) it is heavy in weight; (2) it has small pores; (3) it produces an intense and chronic inflammatory response; and (4) it is made of polypropylene—a material known to degrade when implanted in the human body. (JA 6224:11-6225:3; 6102:16-6103:8; 6490:4-6; 6491:16-6493:2; 6538:8-13). These defects caused the mesh to erode resulting in a number of injuries, including those suffered by Judith Shears. (JA 6201:8–11; 6223:15–6224:4).

An erosion means that the TVT mesh itself has become exposed to other internal organs adjacent to where the mesh is placed, including the urethra, the vagina, or—in this case—the bladder. *Id.* at JA 6020:3–7. When an erosion occurs, it can cause the patient to experience chronic pain, dyspareunia (pain with intercourse), bladder infections, overactive bladder, and the formation of bladder stones. *Id.* at JA 6020:8–12.

2. Judith Shears' Relevant Medical History

Beginning in October 2008, Mrs. Shears presented to her primary care physician with complaints of SUI, intermittent constipation, and a bulging feeling of her uterus which produces some pain with intercourse. (JA 6161:17–6162:8).

Shortly thereafter, Mrs. Shears was referred to a urogynecologist, Dr. Eddie H.M. Sze for evaluation. *Id.* at JA 6163:14–20. Dr. Sze noted that Mrs. Shears’ incontinence was “progressively worsening” and that she had a significant degree of uterine prolapse. *Id.* at JA 6163:21–22; 6164:9-13. Dr. Sze’s treatment plan included a posterior repair (surgical correction of the uterine prolapse) and the placement of a TVT mesh sling to treat her SUI. *Id.* at JA 6166:20–23.

On March 16, 2009, Mrs. Shears underwent surgery at West Virginia University Hospital, where Dr. Sze performed the posterior repair and implanted the TVT mesh. (JA 5585). Initially, Mrs. Shears felt somewhat better—her complaints of leaking, bulging, discomfort, pain with intercourse due to the uterine prolapse had resolved. (JA 6173:17–6174:10; 6176:25–6177:11). But, Mrs. Shears returned to Dr. Sze’s office in April 2012 with new reports of urgency, frequency, and incontinence. *Id.* at JA 6178:8–6179:6.

In September 2013, Mrs. Shears made an appointment to see Dr. Stanley Zaslau after experiencing continued complaints of recurrent urinary tract infections, pelvic pain, frequent urination, burning with urination, leaking urine, and dyspareunia (the medical term for painful sex). *Id.* at JA 6184:4–16; 6185:1–7. These symptoms were incredibly painful for Mrs. Shears; she described the pain as “sharp” and “stabbing.” (JA 6713:4–7). Worse, she testified that “she couldn’t even sit flat” without experiencing intense pain. *Id.* at JA 6713:8–10.

On October 29, 2013, Mrs. Shears underwent a revision procedure performed by Dr. Zaslau, which included the surgical removal or excision of eroded TVT mesh, urethrolisis, and the surgical removal of a bladder stone. (JA 5586). For the first time, Mrs. Shears began to feel relief from the pain. (JA 6713:11–13). However, following this procedure, in February 2014, Dr. Zaslau performed a cystoscopy which revealed more eroded mesh in the bladder (JA 6202:1–13).

Unfortunately, the abdominal and bladder pain, incontinence/leaking urine, and recurrent bladder infections returned. *Id.* at JA 6204:3–10; 6205:14–24; 6208:13–23; 6209:3–16. In addition to those symptoms, Mrs. Shears developed new problems as well, including incomplete bladder emptying, dysuria, and frequency. *Id.* Due to her difficulty voiding, Dr. Zaslau planned to perform a cystoscopy in order to see what, if anything, was obstructing her bladder. *Id.* at JA 6219:18–25. The cystoscopy, revealed two large stones in Mrs. Shears’ bladder and that the TVT was obstructing her bladder outlet. *Id.* at JA 6220:1–18.

On June 25, 2021, Mrs. Shears underwent a second revision surgery performed by Dr. Zaslau which included the removal of the two bladder stones. (JA 5586). Dr. Zaslau told Mrs. Shears that “because she had a history of extruded mesh, [the mesh] was the leading cause of her recurrent bladder stones.” (JA 6466:16–21).

B. Relevant Procedural History

1. The Multi-District Litigation

On June 28, 2013, this case was directly filed by Short Form Complaint in the Ethicon multi-district litigation (“MDL”) consolidated before the Honorable Joseph R. Goodwin in the United States District Court for the Southern District of West Virginia. (JA 48-53); *In re: Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327 (S.D. W. Va.) (hereinafter referred to as the “MDL”). The MDL was formed as a result of the use of transvaginal surgical mesh to treat two pelvic conditions that occur in women: stress urinary incontinence (“SUI”) and pelvic organ prolapse (“POP”). Among all cases, the claims against Ethicon were the same: design defect, failure to warn, negligence, breach of express warranty, breach of implied warranty, and punitive damages. *Id.*

2. The *Mullins* Consolidation

On July 1, 2015, the MDL Judge consolidated thirty-seven (37) cases for trial, including the Shears’ case. This consolidation was referred to as the *Mullins* consolidation. *See Mullins, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-02952 (S.D. W. Va.). The *Mullins* consolidation was made up of thirty-seven (37) plaintiffs all implanted with the same product—Ethicon’s Trans-Vaginal Tape (“TVT”), a product manufactured and designed by Ethicon to treat SUI. The MDL Judge

consolidated the aforementioned cases for trial on the negligence and strict liability design defect claims.

3. Remand to the Northern District of West Virginia

On November 20, 2020, the MDL Judge entered a Transfer Order, remanding nine (9) cases for trial in the venues from which they arose, including the Shears' case. On March 3, 2021, the District Court entered a Scheduling Order, setting a ten (10) day jury trial to commence on March 7, 2022.

4. The District Court grants Ethicon summary judgment on the Shears' strict product liability design defect claim

On February 11, 2022, the District Court held a *Daubert* hearing to enter rulings on outstanding *Daubert* issues left undecided by the MDL Judge. (*See* JA 5461-5584). Before any argument was reached on the *Daubert* issues, the District Court *sua sponte* requested oral argument on Plaintiffs' strict product liability design defect claim—specifically, “the requirement under West Virginia products liability law, as found by Judge Goodwin and as established in the pattern jury instructions, that the alternative feasible design must eliminate the risk of which the plaintiff complains that caused the injuries.” *Id.* at JA 5463:25–5464:12. Following extensive argument on the issue, the District Court ultimately found that the ‘elimination of risk’ standard was “the standard under West Virginia law and the pattern jury instructions.” JA 5469:1–4. The District Court then noted that all of the opinions offered by the Shears' design expert were couched in terms of “reduction” of the

risk as opposed to “elimination.” JA 5465:2-5470:25. After analyzing the Shears’ “reduction of the risk” evidence against the erroneous “elimination of the risk” standard, the District Court excluded the expert opinions underpinning the Shears’ strict product liability claim, effectively granting summary judgment to Ethicon on said claim. *Id.* at JA 5568:8-5570:5.

5. The District Court grants Ethicon judgment as a matter of law on the Shears’ malfunction- based strict product liability claim

At the close of the Shears’ case-in-chief, Ethicon moved for judgment as a matter of law on all of the Shears’ claims. The District Court granted said motion with respect to the Shears’ strict product liability claim based on the Malfunction Theory. (JA 7584-7592). Specifically, the District Court found that despite the fact that the Shears’ produced ample evidence of TVT degradation, the Shears failed to show that the degradation was the result of a product defect. *Id.* at JA 7585-7588.

6. The District Court’s erroneous negligence-based product liability jury instruction (the “Negligence Instruction”)

Ethicon submitted its Second Amended Proposed Jury Instructions on March 13, 2022. Included were several jury instructions that purportedly related to the Shears’ negligence-based product liability. However, Ethicon’s proposed Negligence instructions impermissibly combined elements of both negligence and strict product liability. On March 14, 2022, the Shears submitted their Amended Proposed Jury Instructions, which included the proper instructions for a negligence-

based product liability claim. The District Court rejected the Shears' negligence-based jury instruction and instead adopted Ethicon's proposed instructions. (JA 7593-7617).¹ The Negligence Jury Instruction was subsequently given to the jury.

7. The jury returns a defense verdict.

On March 16, 2022, the jury returned its verdict in favor of Ethicon. (JA 7618-7622). The first question on the verdict form read as follows: "Did the Plaintiffs prove, by a greater weight of the evidence, that the Defendants negligently designed the TVT?" (JA 7618). The jury answered "No." *Id.*

C. Rulings Presented for Review

1. The District Court granted Ethicon summary judgment on the Shears' strict product liability claim based on design defect, finding that the Shears failed to identify an alternative feasible design that completely eliminated the risk of injury to Mrs. Shears. (JA 5593:7–11; 5622:11–13).

2. At the close of the Shears' case-in-chief, the District Court granted Ethicon judgment as a matter of law on the Shears' strict product liability claim based on the malfunction theory, finding that a reasonable juror would be unable to conclude that the malfunctions identified by the Shears were the result of a product defect. (JA 7584 at 2–9).

¹ The District Court's entire Jury Instruction on the Shears' negligence-based product liability claim is reproduced below in Section V(D)(2).

3. The District Court rejected the Shears' proposed jury instruction on their negligence-based product liability claim and improperly instructed the jury on said claim.

IV. SUMMARY OF THE ARGUMENT

A. Under controlling West Virginia law, a plaintiff need only demonstrate that a product was not reasonably safe for its intended use in order to prevail on a strict product liability claim. The West Virginia Supreme Court intentionally adopted a flexible legal standard in light of the fact that no single test could adequately cover every aspect of strict product liability claims. Accordingly, strict product liability claims based on design defect can be proven in a variety of ways. None of these various ways require a plaintiff to prove the existence of a feasible, alternative design that would have eliminated the plaintiff's risk of injury. In fact, such a requirement is contrary to West Virginia law.

B. The Shears adduced sufficient evidence in support of their strict product liability design defect claim under the malfunction theory to survive Ethicon's motion for judgment as a matter of law.

C. The District Court improperly instructed the jury on the Shears' negligence-based strict product liability claim. Under controlling West Virginia law, strict product liability claims and negligence-based product liability claims are separate and distinct. **They have different elements and serve different purposes.**

The Negligence Instruction erroneously combined the elements of these two separate and distinct claims. This erroneous instruction unfairly prejudiced the Shears because said instruction required the Shears to satisfy a much higher evidentiary standard to prevail on their negligence-based product liability claim.

V. ARGUMENT

A. **The District Court improperly granted Ethicon summary judgment on the Shears’ strict product liability design defect claim.**

In the present case, U.S. District Court Judge Irene M. Keeley adopted U.S. District Judge Goodwin’s erroneous ruling in *Mullins v. Ethicon, Inc.*, 2016 U.S. Dist. LEXIS 170445, 2016 WL 7197441, 10 (S.D. W. Va. 2016) (hereafter referred to as “*Mullins 2*”), that in products liability litigation the elimination of risk standard was required under West Virginia law and the pattern jury instructions. As outlined and discussed below, there is no authority from the Supreme Court of Appeals of West Virginia that supports Judge Goodwin’s position on this issue and the reliance of Judge Keeley upon the same.

1. **West Virginia product liability law applies.**

In *Stahle v. CTS Corp.*, 817 F.3d 96, 99 (4th Cir. 2016), the U.S. Court of Appeals for the Fourth Circuit explained that in cases involving diversity jurisdiction:

. . . our role is to apply the governing state law. *See BP Prods. N. Am., Inc. v. Stanley*, 669 F.3d 184, 188 (4th Cir. 2012). **“It is axiomatic that in determining state law a federal court must look first and**

foremost to the law of the state’s highest court, giving appropriate effect to all its implications.” *Assicurazioni Generali, S.p.A. v. Neil*, 160 F.3d 997, 1002 (4th Cir. 1998). If, as here, the state’s highest court has not directly addressed the issue, a federal court “must anticipate how it would rule.” *Liberty Univ., Inc. v. Citizens Ins. Co. of Am.*, 792 F.3d 520, 528 (4th Cir. 2015).

Stahle, at 99 (emphasis added). As explained in detail below, the Supreme Court of Appeals of West Virginia has directly addressed the evidentiary requirements of proving a design defect claim and they do not include a requirement to demonstrate the existence of a feasible alternative design that would eliminate the risk of injury.

2. The Supreme Court of Appeals of West Virginia announces new points of law through Syllabus Points.

In *State v. McKinley*, 234 W. Va. 143, 149, 764 S.E.2d 303 (2014), the Supreme Court of Appeals of West Virginia stated that, “[t]he scope and form of the decisions of [the Supreme Court of Appeals of West Virginia] are primarily governed by the West Virginia Constitution. Our decisions are required to address ‘every point fairly arising upon the record’ and are ‘**binding authority upon any court**’ if concurred in by a majority of the justices. W. Va. Const. art. VIII, § 4.” (Emphasis added).²

According to Syllabus Point 2 of *Walker v. Doe*, 558 S.E.2d 290 (2001) (overruled on other grounds by *McKinley*, *supra*), the Supreme Court of Appeals of

² “No decision rendered by the court shall be considered as binding authority upon any court, except in the particular case decided, unless a majority of the justices of the court concur in such decision.” W. Va. Const. Art. VIII, § 4.

West Virginia “. . . **will use signed opinions when new points of law are announced and those points will be articulated through syllabus points as required by our state constitution.**” (Emphasis added).³ Additionally, “[s]igned opinions containing original syllabus points have the highest precedential value because the Court uses original syllabus points to announce new points of law or to change established patterns of practice by the Court.” Syl. Pt. 1 of *McKinley*, 234 W. Va. 143 (emphasis added).

The Supreme Court of Appeals of West Virginia has further held that, “[s]igned opinions that do not contain original syllabus points also carry significant, instructive, precedential weight because such opinions apply settled principles of law in different factual and procedural scenarios than those addressed in original syllabus point cases.” *Id.* at Syl. Pt. 2. Additionally, “[s]igned opinions, both those including new syllabus points and those not containing new syllabus points, are published opinions of the Court. As such, **they should be the primary sources relied upon in the development of the common law.**” *Id.* at Syl. Pt. 3 (emphasis added).

³ “When a judgment or order of another court is reversed, modified or affirmed by the court, every point fairly arising upon the record shall be considered and decided; the reasons therefor shall be concisely stated in writing and preserved with the record; and it shall be the duty of the court to prepare a syllabus of the points adjudicated in each case in which an opinion is written and in which a majority of the justices thereof concurred, which shall be prefixed to the published report of the case.” *Id.*

Lastly, the West Virginia Supreme Court has stated the following regarding obiter and judicial dicta:

Dicta normally comes in two varieties: obiter dicta and judicial dicta. **Obiter dicta are comments in a judicial opinion that are unnecessary to the disposition of the case. Judicial dicta are comments in a judicial opinion that are unnecessary to the disposition of the case, but involve an issue briefed and argued by the parties.** Judicial dicta have the force of a determination by a reviewing court and should receive dispositive weight in an inferior court. Similarly, obiter dicta of a court of last resort can be tantamount to a decision and therefore binding in the absence of a contrary decision of that court.’ *People v. Williams*, 204 Ill. 2d 191, 788 N.E.2d 1126, 1136, 273 Ill. Dec. 250 (Ill. 2003) (internal quotations and citations omitted).”

Footnote 6, *W. Va. DOT v. Parkersburg Inn, Inc.*, 222 W. Va. 688, 671 S.E.2d 693 (2008)(per curiam)(emphasis added). However, the West Virginia Supreme Court “. . . has made clear that ‘[o]biter dicta or strong expressions in an opinion, where such language was not necessary to a decision of the case, **will not establish a precedent.**’ *In re Assessment of Kanawha Valley Bank*, 144 W.Va. 346, 382-83, 109 S.E.2d 649, 669 (1959).” *Univ. Park at Evansdale, LLC v. Musick*, 238 W. Va. 106, 112, 792 S.E.2d 605 (2016)(emphasis added).

3. Controlling West Virginia law on strict product liability claims based on design defect are contained in *Morningstar*, the seminal West Virginia products liability opinion.

The Supreme Court of Appeals of West Virginia directly addressed the evidentiary basis for a strict product liability claim based on design defect in the

seminal case of *Morningstar v. Black & Decker Mfg. Co.*, 162 W. Va. 857, 253

S.E.2d 666 (1979). In that case, the West Virginia Supreme Court held that:

In this jurisdiction the general test for establishing strict liability in tort is **whether the involved product is defective in the sense that it is not reasonably safe for its intended use**. The standard of reasonable safeness is determined not by the particular manufacturer, but by what a reasonably prudent manufacturer's standards should have been at the time the product was made.

Id. at Syl. Pt. 4 (emphasis added). The West Virginia Supreme Court further held that:

The term “unsafe” imparts a standard that **the product is to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to economic costs, at the time the product was made**.

Id. at Syl. Pt. 5 (emphasis added). The West Virginia Supreme Court went on to explain that:

. . . a defective product may fall into three broad, and not necessarily mutually exclusive, categories: design defectiveness; structural defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions and labels.

Characteristically, under the first two categories of defectiveness the inquiry centers on the physical condition of the product which renders it unsafe when the product is used in a reasonably intended manner. In the third category of defectiveness the focus is not so much on a flawed physical condition of the product, as on its unsafeness arising out of the failure to adequately label, instruct or warn.

Morningstar, 162 W. Va. 888 (emphasis added).

Historically, the United States District Courts in West Virginia have faithfully adhered to these legal tenets. For example, in *Keffer v. Wyeth*, 791 F. Supp. 2d 539 (S.D. W. Va. 2011), a product liability claim involving hormone replacement therapy medications, the defendant sought summary judgment on the plaintiff's strict liability design defect claim to the extent that the claim was based on the existence of a safer alternative design. *Id.* at 547. The plaintiff countered by arguing that proof of a safer alternative design was not required to establish a design defect claim under West Virginia law and, in any event, the plaintiff had come forward with a safer alternative. *Id.*

In response to these arguments, U.S. District Court Judge John T. Copenhaver, Jr., correctly observed as follows:

West Virginia's strict products liability doctrine has its origin in *Morningstar v. Black and Decker Manufacturing Co.*, 162 W. Va. 857, 253 S.E.2d 666 (W. Va. 1979). Syllabus Point 4 of *Morningstar* provides as follows:

In this jurisdiction the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use. The standard of reasonable safeness is determined not by the particular manufacturer, but by what a reasonably prudent manufacturer's standards should have been at the time the product was made.

Id., at Syl. Pt. 4. Generally speaking, "[o]nce it can be shown that the product was defective when it left the manufacturer and that the defect proximately caused the plaintiff's injury, a recovery is warranted." *Id.* at 680. "[A] defective product may fall into three broad, and not necessarily mutually exclusive, categories: design defectiveness;

structural defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions and labels.” *Id.* at 682.

To be sure, the West Virginia Supreme Court has not stated one way or the other whether a design defect claim requires proof of a safer alternative design of the allegedly defective product. See Philip Combs & Andrew Cooke, Modern Products Liability Law in West Virginia, 113 W. Va. L. Rev. 417, 427 (2011) (noting lack of caselaw on the issue). Nevertheless, even if it is not required, offering evidence of a safer alternative is at least one method of showing that a product is “not reasonably safe for its intended use” for the purposes of a design defect claim.

Keffer, 791 F. Supp. 2d 547 (emphasis and underline added). In summary, U.S. District Court Judge Copenhaver correctly concluded that under West Virginia law: (1) there is no requirement to prove a safer alternative design to prevail on a design defect claim; and (2) evidence of a safer alternative design is, “. . . at least one method of showing that a product is “not reasonably safe for its intended use” for the purposes of a design defect claim.” *Id.*

U.S. District Judge Copenhaver’s citation to Modern Products Liability Law in West Virginia is particularly instructive in this case for three reasons. First, Philip Combs, one of the authors of this law review article, is also local counsel for Ethicon in the present matter. Second, in this law review article, the authors lament the fact that tort reform in West Virginia has not yet reached the field of products liability:

Obviously, products liability is an exceptionally important area of the law in this state. And, **due to the fact there has been substantial tort reform in other areas, such as medical malpractice and insurance bad faith litigation, but not in relation to products liability suits, we**

predict that the volume of products liability litigation will continue to increase.

113 W. Va. L. Rev. 421 (emphasis added).

Third, with respect to alternative designs vis-à-vis design defect claims, the authors of that law review article state as follows:

A threshold legal issue is whether the plaintiff, in her affirmative case-in-chief, must prove that there is a feasible, alternative design that will eliminate the risk and render the product “reasonably safe.” In other words, **can the plaintiff merely argue that the manufacturer’s design was flawed or must she also point to a feasible alternative design that appropriately eliminates that particular risk?**

This issue has received little attention from the court because, as a practical matter, plaintiff’s counsel almost always put forth an alternative design even in the absence of a requirement. **The only West Virginia Supreme Court of Appeals case addressing the issue is *Church v. Wesson*, in which the court in a per curiam opinion upheld a directed verdict for the defendant, in a strict liability context, on the ground that the plaintiff failed to establish the feasibility of a proffered alternative design.**

113 W. Va. L. Rev. 427 (emphasis added). Thus, as of 2011, Ethicon’s own counsel recognized that there was no requirement under West Virginia law to offer evidence of a feasible, alternative design that would eliminate the risk of injury in a design defect claim.

U.S. District Court Judge Joseph R. Goodwin initially reached the same conclusion in the consolidated phase of the MDL:

Next, Ethicon asserts that a consolidated trial on design defect is improper because the plaintiff must prove the existence of a safer alternative design, which requires plaintiff-specific evidence.

Specifically, according to Ethicon, the plaintiffs must show “the alternative design would have materially reduced the plaintiff’s injuries.” (Defs.’ Objection [Docket 27], at 3). First of all, **“the West Virginia Supreme Court of Appeals has not stated one way or the other whether a design defect claim requires proof of a safer alternative design of the allegedly defective product.”** *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 547-48 (S.D. W. Va. 2011) (Copenhaver, J.). Admittedly, **whether required or not, evidence on the existence of a safer alternative is certainly relevant**, as explained in *Morningstar* Syllabus Point 5, which states that the “general state of the art of the manufacturing process” should be considered when determining whether a product is “unsafe.” *Morningstar*, 253 S.E.2d at Syl. pt. 5.

But contrary to Ethicon’s position, there is no West Virginia authority requiring plaintiffs to prove, as part of their *prima facie* case, that the proposed safer alternative design would have reduced an individual plaintiff’s specific injuries. In fact, my colleague has recently rejected this position. *See Keffer*, 791 F. Supp. 2d at 548-49 (rejecting the proposition that a plaintiff must prove that an alternative drug design would have specifically prevented her injuries (citing *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 901 (E.D. Va. 2010))). Persuaded by this reasoning, I FIND that plaintiff-specific information is not required to develop or defend against state-of-the-art evidence of a safer alternative design, and Ethicon’s objection is overruled.

Mullins v. Ethicon, Inc., 117 F. Supp. 3d 810 (S.D. W. Va., August 4, 2015) (emphasis added) (hereafter referred to as “*Mullins* 1”).

On June 6, 2016, a mere eleven months later, Ethicon filed a motion for reconsideration of this order (the “Motion to Reconsider”). What precipitated the Motion to Reconsider? Did the Supreme Court of Appeals of West Virginia publish a new syllabus point requiring proof of a feasible, alternative design that would

eliminate the risk of injury? No. The West Virginia Pattern Jury Instructions (“WVPJIs”) were published.

4. The WVPJIs

The WVPJIs were originally published in June of 2016. According to the Caveat contained in the Preface to the WVPJI’s:

These are pattern jury instructions that were written to help trial judges and lawyers instruct the jury in civil case. THEY ARE NOT BINDING ON THE TRIAL JUDGE. Although they are pattern instructions, **the lawyers have an obligation to object and point out any errors in any pattern jury instruction that is offered by a party or which a trial judge indicates will be read to a jury. On appeal, the Supreme Court will not be bound by the correctness of these pattern jury instructions. It is incumbent upon the lawyers in a trial to ensure the correctness of any pattern jury instruction that may be read to a jury.**

Id. (capitalization in original, bold added). According to the Drafting Note contained in the Preface, the WVPJIs, while not binding, “. . . have gone through multiple edits and revisions after extensive research and editing by the reporters, the review committees, Judge Alsop, and Justice Ketchum.” *Id.*

Section 400 of the WVPJIs covers products liability. Conspicuously absent from the Motion to Reconsider is the fact that Philip Combs, local counsel for Ethicon, was the reporter for Section 400. Contained within Section 400 is WVPJI § 411, entitled, “Design Defect – Necessity of an Alternative, Feasible Design.” It states that, “There are many designs which, although they may eliminate a particular risk, are not practicable to produce. **To prove that a design is defective, [name of**

plaintiff] must prove that was an alternative, feasible design that eliminated the risk that injured [him/her].” *Id.* (Brackets and italics in original, bold added.)

Mr. Combs cited only two cases as the original legal basis for WVPJI § 411: *Morningstar, supra*, and *Church v. Wesson*, 182 W. Va. 37, 385 S.E.2d 393 (1989).⁴ Neither case contains any such requirement. Moreover, just five years earlier, Mr. Combs stated in his law review article that *Church, supra*, (a *per curiam* opinion of very limited precedential value) merely upheld a directed verdict for the defendant, because the plaintiff failed to establish the feasibility of a proffered

⁴ The WVPJIs were supplemented in 2017. The supplemented version of WVPJI 411 contains a reference to *Mullins 2* and *Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. 2017). Unsurprisingly, the *Nease* opinion makes absolutely no mention of a requirement to prove the existence of feasible alternative design that would eliminate the risk of injury. Instead, the Court in *Nease* merely stated that:

While it is true that West Virginia law on the matter is not crystal clear, we agree with Ford that *Morningstar* “can only be read to require the production of evidence on reasonable alternative design, to gauge what ‘should have been.’” Restatement (Third) of Torts: Products Liability § 2, Reporter's Note (1998). Although *Morningstar* does not use the phrase “alternative design,” a plaintiff in a design case, for all practical purposes, **must identify an alternative design in order to establish the “state of the art.”**

Nease, 848 F.3d 233 (emphasis added). The *Nease* opinion makes clear that a reasonable alternative design goes only to establishing the state of the art. It is not a requirement to prove a design defect, in general, in order to prevail on a design defect strict product liability claim. Moreover, the *Nease* opinion makes clear that the alternative design need only make the product safer: not entirely eliminate the risk of injury. In fact, the phrase “safer alternative” appears seven times in the opinion. The word “eliminate” appears only once and comes from a citation to a handbook produced by Ford.

alternative design. 113 W. Va. L. Rev. 427. Significantly, the unsigned *Church* opinion contained only two Syllabus Points. The first relates to the standard for a directed verdict and the second repeats Syllabus 4 of *Morningstar*, reiterating the West Virginia Supreme Court's adherence to that binding legal standard. Thus, based on Mr. Combs' very admissions in his law review article, WVPJI § 411 is simply an attempt at tort reform disguised as legal authority.

5. Ethicon's Motion to Reconsider and *Mullins* 2.

In its Motion to Reconsider, Ethicon's counsel, ". . . respectfully requests that the Court reconsider [*Mullins* 1] in light of the West Virginia Supreme Court's recent statement of West Virginia law [WVPJI § 411]." (JA 61) Ethicon's counsel went on to state that:

In June 2016, the West Virginia Supreme Court of Appeals released its Pattern Jury Instructions for Civil Cases, in which it clarified that (a) there is an alternative, feasible design requirement in West Virginia, and (b) the alternative design requirement requires proof that it would eliminate the risk that injured the plaintiff.

JA 61. These statements are patently false.

In reality, the WVPJIs are not a statement of West Virginia law made by the Supreme Court of Appeals of West Virginia. Most importantly, WVPJI § 411 assuredly did not clarify that a feasible, alternative design that would eliminate the risk of injury was a requirement of design defect claim.

As noted above in *Walker*, the Supreme Court of Appeals of West Virginia uses “. . . signed opinions when new points of law are announced and those points will be articulated through syllabus points as required by our state constitution.” To be perfectly clear, there is no authored opinion from the West Virginia Supreme Court of Appeals containing a syllabus point requiring a plaintiff making a claim for strict liability in a products liability case to identify an alternative design that would completely eliminate the risk of the particular injury. Nor does any case, authored or otherwise, from the Supreme Court of Appeals of West Virginia contain any obiter dicta that would impose such a requirement.

Moreover, the WVPJIs, including WVPJI 411, were signed by a single West Virginia Supreme Court Justice, falling far short of the majority required by Article VIII, § 4 of the West Virginia Constitution. *See McKinley, supra*. In fact, because WVPJI 411 does not appear in a single judicial opinion, it qualifies as neither obiter nor judicial dicta. *See Parkersburg Inn, supra*. Thus, WVPJI 411 has no precedential value whatsoever.

The only other way that the Supreme Court of Appeals of West Virginia could conceivably have adopted the WVPJIs is through the administrative process set forth in Article VIII, Section 3 of the West Virginia Constitution and W. Va. Code

§ 51-1-4.⁵ The Administrative Orders of the Supreme Court of Appeals of West Virginia from 2010 to present can be found on the West Virginia Supreme Court's website.⁶ These Administrative Orders never even so much as mention the WVPJIs, much less demonstrate compliance with the process mandated by W. Va. Code § 51-1-4. Simply put, the West Virginia Supreme Court clearly never adopted the WVPJIs through the administrative process as mandated by the West Virginia Constitution and W. Va. Code § 51-1-4.

Unfortunately, the false statements contained in Ethicon's Motion to Reconsider persuaded U.S. District Court Judge Goodwin to reverse his ruling in

⁵ Article VIII, § 3 of the West Virginia Constitution states, in pertinent part, that, "[t]he court shall have power to promulgate rules for all cases and proceedings, civil and criminal, for all of the courts of the State relating to writs, warrants, process, practice and procedure, which shall have the force and effect of law.

W. Va. Code § 51-1-4 states, in pertinent part, that, "The Supreme Court of Appeals may, from time to time, make and promulgate general rules and regulations governing pleading, practice and procedure in such court and in all other courts of record of this State. . . The Judicial Council of West Virginia is hereby designated as advisory committee to make observation and report to the Supreme Court of Appeals, from time to time, such recommendations as may, in its judgment, be proper; and **all rules promulgated by the Supreme Court of Appeals under the authority of this section shall, before taking effect, be referred to the Chairman of the Judicial Council, the President of the West Virginia Bar Association and to the judge of every court affected thereby.**" (Emphasis added.)

⁶ <http://www.courtswv.gov/legal-community/recent-rules-orders.html> (last accessed on June 30, 2022)

Mullins 1. In the Order granting the Motion to Reconsider, U.S. District Court Judge

Goodwin noted that:

. . . the West Virginia Supreme Court has adopted the following pattern jury instruction:

There are many designs which, although they may eliminate a particular risk, are not practicable to produce. To prove that a design is defective, [name of plaintiff] must prove that there was an alternative, feasible design that eliminated the risk that injured [him/her].

W. Va. P.J.I. § 411.

Mullins, 2016 U.S. Dist. LEXIS 170445, 2016 WL 7197441, 10. U.S. District Court

Judge Goodwin went on to rule as follows:

“The ultimate responsibility of the federal courts, at all levels, is to reach the correct judgment under law.” *Am. Canoe Ass’n, Inc.*, 326 F.3d at 515. To the extent it requests reconsideration of part of the court’s August 4, 2015, Memorandum Opinion & Order [ECF No. 38], Ethicon’s Motion is **GRANTED**. The court **FINDS** that in a West Virginia strict liability design defect products liability case, a plaintiff must prove that there was an alternative, feasible design—existing at the time of the product’s manufacture—that would have eliminated the risk that injured the plaintiff.

Mullins 2 at 21 (capitalization and bold in original). In the present case, U.S. District Court Judge Irene M. Keeley adopted U.S. District Judge Goodwin’s erroneous ruling in *Mullins* 2.

6. WVPJI § 411 is in direct conflict with controlling West Virginia Case Law.

In addition to the fact that the Supreme Court of Appeals of West Virginia has never adopted a requirement to prove the existence of a feasible, alternative design that would eliminate the risk of injury in a design defect case, such a requirement is contrary to controlling West Virginia law.

- i. A requirement to prove the existence of an alternative, feasible design that would eliminate the risk of injury places a greater burden of proof on a plaintiff than what is required by West Virginia law.**

In order to prevail on a strict liability claim based on a design defect claim under West Virginia law, a plaintiff needs to show only that the product was not reasonably safe for its intended use. *See* Syl. Pt. 4 of *Morningstar*, 162 W. Va. 857. The safeness of a product is, “. . . to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to economic costs, at the time the product was made.” *Id.* at Syl. Pt. 5.

The Supreme Court of Appeals went on to explain the role of the risk/utility analysis in establishing a product defect:

We believe that a risk/utility analysis does have a place in a tort product liability case by setting the general contours of relevant expert testimony concerning the defectiveness of the product. In a product liability case, the expert witness is ordinarily the critical

witness. **He serves to set the applicable manufacturing, design, labeling and warning standards based on his experience and expertise in a given product field.**

Through his testimony the jury is able to evaluate the complex technical problems relating to product failure, safety devices, design alternatives, the adequacy of warnings and labels, as they relate to economic costs. **In effect, the expert explains to the jury the risk/utility standards and gives the jury reasons why the product does or does not meet such standards, which are essentially standards of product safety.**

Morningstar, 162 W. Va. 887 (emphasis added).

Given these inherent complexities, the West Virginia Supreme Court intentionally adopted a flexible standard for proving a product defect:

We also recognize that **in this opinion we cannot formulate a solution for every problem that may arise in future product liability cases.** We do state that the cause of action rests in tort, and that **the initial inquiry, in order to fix liability on the manufacturer, focuses on the nature of the defect and whether the defect was the proximate cause of plaintiff's injury.**

Characteristically, under the first two categories of defectiveness the inquiry centers on the physical condition of the product which renders it unsafe when the product is used in a reasonably intended manner.

Id. at 888 (emphasis added) (emphasis added).

Under this controlling case law, a design defect claim can be proven in myriad ways by simply demonstrating that the product in question falls short of what a reasonably prudent manufacturer would accomplish with regard to product safety. For example, a plaintiff can prove a design defect claim under West Virginia law by showing that the product in question fails to meet the safety standards of the general

state of the art. *See* Syl. Pt. 5 of *Morningstar*, *supra*. In many cases, state of the art designs cannot completely eliminate every risk associated with a product. Furthermore, some products are so inherently dangerous that they simply cannot be made safe. Does West Virginia product liability foreclose a strict liability design defect claim in such cases because no feasible, alternative design that would eliminate the risk of injury exists? Based on Syllabus Point 4 of *Morningstar*, the answer is a resounding “NO!”

Additionally, West Virginia law expressly allows for a strict product liability claim even where the plaintiff cannot identify the specific defect:

“Circumstantial evidence may be sufficient to make a *prima facie* case in a strict liability action, **even though the precise nature of the defect cannot be identified, so long as the evidence shows that a malfunction in the product occurred that would not ordinarily happen in the absence of a defect.** Moreover, the plaintiff must show there was neither abnormal use of the product nor a reasonable secondary cause for the malfunction.” Syl. Pt. 3, *Anderson v. Chrysler Corp.*, 184 W. Va. 641, 403 S.E.2d 189 (1991).

Syl. Pt. 9, *Adkins v. K-Mart Corp.*, 204 W. Va. 215, 511 S.E.2d 840 (1998) (emphasis added). This is commonly referred to as the “Malfunction Theory.” Under the Malfunction Theory, a plaintiff need not identify the specific design defect to prevail on a strict product liability claim. It would defy logic to simultaneously require that same plaintiff to demonstrate the existence of feasible, alternative design that would eliminate the risk created by the unidentifiable defect.

Moreover, a plaintiff can prove a product defect where the product in question fails the risk/utility test. As the Supreme Court of Appeals of West Virginia observed in *Morningstar, supra*, the “. . . risk/utility analysis does have a place in a tort product liability case by setting the general contours of relevant expert testimony concerning the defectiveness of the product.” *Id.*, at 887. The relevant factors in the risk/utility test include:

- (1) The usefulness and desirability of the product -- its utility to the user and to the public as a whole.
- (2) The safety aspects of the product -- the likelihood that it will cause injury, and the probable seriousness of the injury.
- (3) **The availability of a substitute product which would meet the same need and not be as unsafe.**
- (4) The manufacturer’s ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
- (5) The user’s ability to avoid danger by the exercise of care in the use of the product.
- (6) The user’s anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
- (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Morningstar, 162 W. Va. 857, at FN 20 (quoting *Cepeda v. Cumberland Engineering Co.*, 76 N.J. 152, 386 A.2d 816, 826-827 (1978) (overruled on other

grounds by *Suter v. San Angelo Foundry & Mach. Co.*, 81 N.J. 150, 406 A.2d 140, (1979)) (emphasis added). Notably, the risk/utility analysis takes into account numerous factors, including both safer product alternatives and the defendant's ability to eliminate the unsafe character of the product. In direct conflict with the risk/utility analysis, WVPJI § 411 impermissibly restricts said analysis to a single factor: the availability of a feasible, alternative design that eliminates the risk of injury.

In Summary, WVPJI § 411 impermissibly eliminates a plaintiff's ability to prove a design defect through evidence of either a safer or the safest design under the relevant state of the art where the safer or safest design was incapable completely eliminating the risk that injured the plaintiff. *See* Syl. Pts. 4 and 5 of *Morningstar*, *supra*. Additionally, WVPJI § 411 impermissibly eliminates a plaintiff's ability to prove a design defect through circumstantial evidence under the malfunction theory. *See* Syl. Pt. 9 of *Adkins*, *supra*. Furthermore, WVPJI § 411 entirely eliminates the risk/utility analysis. In essence, WVPJI § 411 unreasonably requires plaintiffs to demonstrate that a defect-free product was feasible under the relevant state of the art, even where the specific product defect cannot be identified and the product fails the risk/utility test. Such a requirement is completely contrary to controlling West Virginia law.

As explained above, WVPJI § 411 completely displaces *Morningstar*'s intentionally flexible standard in every case where no feasible, alternative design would completely eliminate the risk of injury to a plaintiff. Such a rigid rule, in effect, eviscerates strict product liability claims based on design defect where feasible, *safer* alternative designs exist which would have *reduced* the risk of injury, where the specific design defect *cannot be identified* and where that product *fails* the risk/utility test.

The Supreme Court of Appeals of West Virginia expressly avoided such a rigid standard in *Morningstar, supra*. Accordingly, WVPJI § 411 is an incorrect statement of law and the District Court erred in relying upon it in granting summary judgment to Ethicon on the Shears' design defect strict product liability claim.

ii. The West Virginia Supreme Court of Appeals has expressly rejected the requirement to prove the existence of a feasible, alternative design that would eliminate the risk of injury.

In addition to articulating the legal standard for proving a product defect, *Morningstar* also expressly rejected the *Rylands v. Fletcher* Doctrine: “[w]e decline to adopt the *Rylands v. Fletcher* Doctrine into our tort product liability law.” *Morningstar*, 162 W. Va. 857, at Syl Pt. 8. In support of this ruling, the West Virginia Supreme Court explained as follows:

We are asked in the final part of the certification whether the power saw is an inherently dangerous product under the *Rylands v. Fletcher* Doctrine, which declared that those conditions or activities which are intrinsically dangerous will result in liability even though there is no

proof of any negligence. The doctrine originally arose from cases involving dangerous activities conducted on one's property which escaped control and damaged others in their person or property. We have recognized the *Rylands* Doctrine in several cases, but none involved a product placed in commerce. *See, e.g., Whitney v. Ralph Myers Contracting Corp.*, 146 W. Va. 130, 118 S.E.2d 622 (1961) (blasting operations); *Weaver Mercantile Co. v. Thurmond*, 68 W. Va. 530, 70 S.E. 126 (1911) (water escaping from tanks).

We are not cited, nor have we found, any authority which suggests that the *Rylands v. Fletcher* Doctrine has been imported wholesale into the product liability field. **Its essential characteristic is that the activity or object is abnormally or exceptionally dangerous. W. Prosser, The Law of Torts (4th ed. 1971) § 78. In the ordinary product liability case, the product, if safely made, is not dangerous, but becomes so only by virtue of a defect.**

***Rylands* looks only to the resulting harm and creates absolute liability on the part of the defendant and no negligence or defect need be shown.** The defendant is an insurer -- a standard which the overwhelming majority of courts refuses to impose on the manufacturer of a product.

Morningstar, 162 W. Va. 891 (emphasis added, some internal citations omitted).

Like the *Rylands v. Fletcher* Doctrine, WVPJI § 411 looks only to the resulting harm caused by the product and creates absolute liability for the defendant for failing to adopt a feasible, alternative design that would have eliminated the risk of injury where, where such a design exists. The Supreme Court of Appeals of West Virginia has expressly rejected such an approach. Instead, strict product liability law in West Virginia focusses on the defective condition of the product itself. *See* Syl. Pts. 4 and 5 of *Morningstar*, *supra*. Accordingly, WVPJI § 411 is an incorrect

statement of law and the District Court erred in relying upon it in granting summary judgment to Ethicon on the Shears' design defect strict product liability claim.

7. The Shears came forward with sufficient evidence to overcome summary judgment on their design defect claim under controlling West Virginia law.

When analyzed under controlling West Virginia law, the Shears presented sufficient evidence to create genuine issues of material fact supporting their strict product liability claim based on design defect.

i. Standard of Review on Order Granting Summary Judgment.

In *Wingate v. Fulford*, 987 F.3d 299, 304 (4th Cir. 2021), the U.S. Court of Appeals for the Fourth Circuit reiterated that:

We review a district court's grant of summary judgment *de novo*, using the same standard applied by the district court. *Henry v. Purnell*, 652 F.3d 524, 531 (4th Cir. 2011) (en banc). **Summary judgment is only appropriate if "no material facts are disputed and the moving party is entitled to judgment as a matter of law."** *Id.* (internal quotation marks omitted).

Wingate, at 304 (emphasis added).

ii. Under the appropriate legal standard for design defect, numerous issues of material fact preclude summary judgment.

As explained in detail above in Section V(A)(3), to survive summary judgment on their design defect strict product liability claim, the Shears were required to come forward with evidence showing that the TVT at issue in the underlying matter was not reasonably safe for its intended use. *See* Syl. Pts. 4 and 5

of *Morningstar*, *supra*. The Shears satisfied this burden by adducing evidence of feasible, alternative designs that were safer than Ethicon's TVT. Specifically, the Shears admitted evidence that other types of mesh—namely, Ultrapro and PVDF—greatly reduce the risk of erosion, scarring, chronic pain, and other issues that are commonly, or ordinarily, seen with TVT mesh. (*See* JA 6661:24; 2721:16–2722:11).

Furthermore, designated testimony from the deposition of Dr. Uwe Klinge, one of the Shears' experts, demonstrates that Ultrapro and PVDF were alternative, feasible designs. *See id.* at JA 2909:14–2910:8 (confirming Ultrapro had been used and researched by Ethicon prior to 2009); *id.* at JA 2687:11–19 (explaining Ultrapro has larger pores and is lighter in weight than Prolene); *id.* at JA 2759:24–2762:6 (confirming PVDF had been used by Ethicon for research since 1999); *id.* at JA 2765:19–2766:5; 2782:19–23 (opining that PVDF is a safer alternative to polypropylene and is the best polymer for mesh implantation).

At trial, the testimony and evidence demonstrated that the risk that injured Mrs. Shears was the heavy weight, small pore, sharp edged nature of the TVT as well as the fact that polypropylene (which makes up the TVT) degrades *in vivo*. (JA 6200:21–6201:11; 6210:6–8; 6223:15–6224:4; 6771:15–6772:21). Indeed, the two alternative designs proffered by Plaintiffs—Ultrapro and PVDF—eliminate these risks which caused Mrs. Shears' injury. (*See* JA 2687:11–19; 2765:19–2766:5; 2782:19–23) (explaining that Ultrapro eliminates the risks of heavy weight and small

pore mesh as Ultrapro is a lightweight, large pore mesh whereas PVDF eliminates the risk of *in vivo* degradation).

B. The District Court improperly granted Ethicon’s Motion for Judgment as a Matter of Law on the Shears’ strict liability design defect claim under the malfunction theory.

1. Standard of Review on Order Granting Judgment as a Matter of Law.

In *Fry v. Rand Constr. Corp.*, 964 F.3d 239, 244 (4th Cir. 2020), the U.S. Court of Appeals for the Fourth Circuit reiterated that:

We review *de novo* the district court's grant of a Rule 50(a)(1) motion for judgment as a matter of law. *Myrick v. Prime Insurance Syndicate, Inc.*, 395 F.3d 485, 489 (4th Cir. 2005). In conducting our review, we apply the same standard used for granting summary judgment. *See Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 150, 120 S. Ct. 2097, 147 L. Ed. 2d 105 (2000). Under Rule 50, a district court may grant the defendant’s motion only when the plaintiff has been fully heard on a claim and the evidence presented, combined with all permissible inferences, does not provide a legally sufficient basis for a reasonable jury to find in the plaintiff’s favor. Fed. R. Civ. P. 50(a)(1). “If a verdict in favor of the nonmoving party ‘would necessarily be based upon speculation and conjecture,’ judgment as a matter of law must be entered in the moving party’s favor. However, ‘**[i]f the evidence as a whole is susceptible of more than one reasonable inference, a jury issue is created and a motion for judgment as a matter of law should be denied.**’” *Fontenot v. Taser International, Inc.*, 736 F.3d 318, 332 (4th Cir. 2013) (quoting *Myrick*, 395 F.3d at 489-90).

Fry, 964 F.3d 244 (emphasis added).

2. Numerous issues of material fact preclude judgment as a matter of law on the Shears' strict liability design defect claim under the malfunction theory.

As noted above in Section V(A)(6)(i), “[c]ircumstantial evidence may be sufficient to make a prima facie case in a strict liability action, even though the precise nature of the defect cannot be identified, so long as the evidence shows that a malfunction in the product occurred that would not ordinarily happen in the absence of a defect.” Syl. Pt. 9, *Adkins*, 204 W. Va. 215 (internal citation omitted). The Shears submitted sufficient evidence for a reasonable juror to conclude that Ethicon’s mesh malfunctioned and that said malfunction would not ordinarily happen in the absence of a defect. Specifically, the Shears presented the following evidence to the jury in support of their Malfunction Theory strict product liability claim:

In as early as July 1998, Ethicon knew, acknowledged, and concealed the fact that mesh erosions were a problem which arises rather commonly in practice and internally recognized that physicians would “want to see the rates of erosion are either low, very low, or nonexistent.” (JA 6078:17–23). The Shears presented evidence that the TVT mesh degrades and erodes inside the body and that such a malfunction would not ordinarily occur absent a defect (or rather multiple defects). (JA 6771:15–6772:21).

The Shears’ expert, Dr. Bruce Rosenzweig, a renowned urogynecologist with a subspecialty in female pelvic medicine and reconstructive surgery, testified that

the polypropylene TVT mesh is not supposed to erode into neighboring organs, and it is not supposed to cause pain. (JA 6018:18–6020:3). In fact, Ethicon’s own experts as well as Mrs. Shears’ implanting physician, Dr. Zaslau, all testified that erosion, pain upon palpation, and the need for mesh removal—all of which were experienced by Mrs. Shears—should not occur. (JA 6928:19–6929:4) “Q. [Is TVT] intended to erode? A. No, it is not. Q. Is it intended to cause bladder stones? A. It’s – no. . . . Q. Is it intended to produce pain on palpation? A. That is not an intention of the device. Q. It is intended to be a permanent device, right? A. Prolene mesh is intended to be a permanent implant, yes.” (JA 6928:19–6929:4); “Q. TVT’s not supposed to erode, correct? A. Correct. Q. TVT’s not supposed to cause pain when it’s palpated, correct? A. Correct. Q. TVT’s not supposed to be removed, correct? A. Yes.” (JA 7066:16–22).

Dr. Rosenzweig explained that erosion and pain occur because polypropylene is subject to degradation and has the following undesirable characteristics: heavy weight, small pore size, and sharp edges. (JA 6107:17–23; 6201:8–11). Consequently, when the TVT erodes and produces pain, it is not functioning as intended. *Id.* at JA 6019:4–7.

Dr. Rosenzweig also testified that there was no abnormal use of Mrs. Shears’ TVT and that other potential causes for the malfunction of the TVT did not occur. *Id.* at JA 6225:17–18. “Q. Was there any abnormal use of the TVT? A. No.”; (JA

6226:15–18) “Q. From your review of the records, Doctor, were there any other causes that explained why the TVT eroded in Judy’s bladder? A. No.”. Specifically, Dr. Rosenzweig ruled out the following other potential causes of device malfunction (i.e., causes of Mrs. Shears’ mesh erosion): that Mrs. Shears implanting physician, Dr. Sze, could have caused injury to the bladder during the implantation procedure (*id.* at JA 6171:3–8); that Dr. Sze placed any mesh into the bladder during the implantation procedure (*id.* at 6171:9–17); that the implantation procedure itself caused any complications (*id.* at 6172:3–5).

C. The District Court’s Negligence Instruction was erroneous and seriously prejudiced the Shears’ negligence-based product liability claim.

1. Standard of Review on Jury Instructions.

In *Hardin v. Ski Venture*, 50 F.3d 1291, 1293 (4th Cir. 1995), the U.S. Court of Appeals for the Fourth Circuit recognized that, “[w]hile the content of jury instructions in a diversity case is a matter of state law, the form of those instructions is governed by federal law.” (Internal citation omitted). In Syllabus Point 4 of *Alley v. Charleston Area Med. Ctr., Inc.*, 216 W. Va. 63, 602 S.E.2d 506 (2004), the Supreme Court of Appeals of West Virginia held that “[a]n instruction is proper if it is a correct statement of the law and if there is sufficient evidence offered at trial to support it.” Syl. Pt. 5, *Jenrett v. Smith*, 173 W.Va. 325, 315 S.E.2d 583 (1983).”

According to *United States v. Miltier*, 882 F.3d 81 (4th Cir. 2018), the U.S. Court of Appeals for the Fourth Circuit reviews:

. . . a district court’s decision to give a particular jury instruction for abuse of discretion, *United States v. Kivanc*, 714 F.3d 782, 794 (4th Cir. 2013), and **review whether a jury instruction incorrectly stated the law de novo**, *United States v. McLaurin*, 764 F.3d 372, 378-79 (4th Cir. 2014). We must determine “whether the instructions construed as a whole, and in light of the whole record, **adequately informed the jury of the controlling legal principles without misleading or confusing the jury to the prejudice of the objecting party.**” *Noel v. Artson*, 641 F.3d 580, 586 (4th Cir. 2011) (internal quotation marks omitted). “Even if a jury was erroneously instructed, however, we will not set aside a resulting verdict **unless the erroneous instruction seriously prejudiced the challenging party’s case.**” *Bunn v. Oldendorff Carriers GmbH & Co. KG*, 723 F.3d 454, 468 (4th Cir. 2013) (emphasis in original) (internal quotation marks omitted).

Miltier, 882 F.3d 89 (emphasis added).

2. The Negligence Instruction incorrectly stated the law.

The law governing negligence-based product liability claims is simple and straightforward. With respect to negligence, the West Virginia Supreme Court has held that, “[n]egligence is conduct unaccompanied by that degree of consideration attributable to the man of ordinary prudence under like circumstances.” Syl. Pt. 1, *Honaker v. Mahon*, 210 W.Va. 53, 552 S.E.2d 788 (2001). “To recover in an action based on negligence the plaintiff must prove that the defendant was guilty of primary negligence and that such negligence was the proximate cause of the injury of which the plaintiff complains.” Syl. Pt. 1, *Atkinson v. Harman*, 151 W. Va. 1025, 158 S.E.2d 169 (1967) (internal citation omitted).

Furthermore, controlling West Virginia law makes clear that strict product liability claims and negligence-based product liability claims are separate and distinct:

Product liability actions may be premised on **three independent theories - strict liability, negligence, and warranty. Each theory contains different elements which plaintiffs must prove in order to recover.** No rational reason exists to require plaintiffs in product liability actions to elect which theory to submit to the jury after the evidence has been presented when they may elect to bring suit on one or all of the theories.

Syl. Pt. 6, *Ilosky v. Michelin Tire Corp.*, 172 W. Va. 435, 307 S.E.2d 603 (1983)

(emphasis added). As explained in detail below, the

The Negligence Instruction began as follows:

Claim of Negligent Design

The Plaintiffs claim that the Defendants negligently designed the TVT mid-urethral sling resulting in a defect that proximately caused Mrs. Shears' injuries. The Defendants deny any negligence and deny that any defect in the TVT caused Mrs. Shears' injuries. The Defendants further assert that Mrs. Shears' alleged injuries in whole or in part are due to other causes and that she assumed the risk of her injuries.

To find that the Plaintiffs are entitled to recover under their negligent design claim, they must prove by a greater weight of the evidence:

1. That the Defendants negligently designed the TVT;
2. That the Defendants' negligence resulted in a defect in the TVT; and
3. That the defect in the TVT proximately caused Mrs. Shears' injuries.

a. Negligent Design

You should first consider whether the Defendants negligently designed the TVT. A medical device company, such as Ethicon, is negligent if it fails to use the amount of care in designing a product that a reasonably careful medical device company would use in similar circumstances to avoid exposing others to a foreseeable risk of harm.

JA 7605. Had the District Court stopped there, the Negligence Instruction would have been a proper statement of West Virginia law. However, the District Court went on to further instruct the jury as follows:

In considering whether the Defendants used reasonable care in designing the TVT, you should balance what the Defendants knew or should have known about the likelihood and seriousness of potential harm from the TVT against the burden of adopting a safer, alternative design to reduce or avoid the harm. In other words, if you decide that the potential harm from the TVT is great and the burden of adopting a safer, alternative design is low, you may find that the Defendants failed to use reasonable care in designing the TVT. On the other hand, if you decide that the burden of adopting a safer, alternative design is high and the potential harm from the TVT is low, then you may find that the Defendants did use reasonable care.

In determining the burden of adopting a safer, alternative design, you may consider the alternative design's cost and disadvantages. For example, if you determine that the cost of a safer, alternative design is high and it significantly impairs the utility of the device, the burden of adoption will be high. Conversely, if you determine that the cost of a safer, alternative design is low and it doesn't impair the utility of the device, the burden of adoption will be low. Additionally, to be considered by you, a safer, alternative design must have been feasible in 2009, the year Mrs. Shears was implanted with the TVT. Feasible means that the alternative design was practicable, even if such a design was not adopted by any manufacturer, or even considered for commercial use, in 2009.

Id. at JA 7605-7606 (bold and underline added). After the bolded clause, the Negligence Jury Instruction completely diverges from the controlling West Virginia law and begins to impermissibly blend elements of strict product liability claims with negligence-based product liability claims. In fact, WVPJI § 425, approved by Ethicon's own counsel, replaces the underlined clause in the portion of the

Negligence Instruction quoted directly above with following clause: “. . . taking safety measures to reduce or avoid the harm.” JA Add. 3. WVPJI § 425, as written, makes absolutely no mention of a “safer alternative design.”

Like the non-existence of a requirement to show a feasible, alternative design that would eliminate the risk of injury to prevail on a strict product liability design defect claim, the West Virginia Supreme Court has never required a plaintiff in a negligence-based product liability to demonstrate the existence of a safer alternative design that would reduce or avoid the harm. This requirement was simply concocted by Ethicon’s counsel. Unfortunately, the erroneous instruction did not stop there. The District Court went on to instruct the jury as follows:

b. Design Defect

If you determine that the Defendants negligently designed the TVT, you must consider whether that negligence resulted in a defect in the TVT. **A product is defective if it is not reasonably safe for its intended use. A product defect may be established by evidence proving that there was a design defect, meaning the product failed to perform safely when used in its reasonably intended manner.** In evaluating whether the TVT was reasonably safe for its intended use, a medical device company, such as Ethicon, is not required to design the safest possible product, or a safer product than the one it did design, so long as the product was reasonably safe for its intended use.

JA 7606-7607 (emphasis added).

The sentences emphasized above come directly from Syllabus Point 4 of *Morningstar, supra*, relating to strict liability claims: “[i]n this jurisdiction the general

test for establishing **strict liability** in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use.” (Emphasis added).

After erroneously instructing the jury that negligence-based product liability claims require the same proof as strict product liability claims, the District Court went on to erroneously instruct the jury that it should consider the risk-utility analysis in assessing the Shears’ negligence-based product liability claim:

i. Risk/Utility Analysis

To determine whether a design was defective or not reasonably safe for its intended use, you should consider whether the benefits of the design outweigh the risks. To make this decision, you may consider the following:

1. The potential harm resulting from the design of the TVT;
2. The likelihood that the harm would occur;
3. The feasibility of a safer, alternative design at the time of Mrs. Shears’ surgery in 2009;
4. The cost of an alternative design;
5. The disadvantages of an alternative design; and
6. The usefulness and desirability, or utility, of the product.

JA 7607.

The West Virginia Supreme Court has never held that the risk/utility analysis has any application whatsoever to negligence-based product liability claims. However, as noted above in Section V(A)(6)(i), the Supreme Court of Appeals of

West Virginia has stated that, “[w]e believe that a risk/utility analysis does have a place in a tort product liability case by setting the general contours of relevant expert testimony **concerning the defectiveness of the product.**” *Morningstar*, 162 W. Va. 887 (emphasis added). Defectiveness is a component of a strict product liability claim: not a negligence-based product liability claim. *See Morningstar, Honaker, and Atkinson, supra*. Moreover, in his law review article, Mr. Combs mentions the risk-utility analysis exclusively in the section related to strict product liability claims based on design defect. *See Modern Products Liability Law in West Virginia*, 113 W. Va. L. Rev. 417, 425-426.

As explained in detail above in Section V(A)(1-7), there is absolutely no requirement under West Virginia law to prove the existence of a feasible, alternative design that would eliminate the risk of injury in strict liability claim. Similarly, there is no requirement under West Virginia law for a plaintiff to show the existence of a safer alternative design in a negligence-based product liability claim. Nonetheless, the District Court further instructed the jury as follows:

ii. Safer, Alternative Design

In addition to weighing the risk and utility of the TVT, to prove that a design is defective, **the Plaintiffs must also prove that there was a safer, alternative design that would have reduced or avoided the risk that injured Mrs. Shears.** There are many designs, however, which, although they may reduce or avoid a particular risk, are not practicable. Additionally, to be considered, a safer, alternative design must have been feasible in 2009, the year Mrs. Shears was implanted with the TVT. Feasible means that the alternative design was

practicable, even if such a design was not adopted by any manufacturer, or even considered for commercial use, at the time of Mrs. Shears' surgery in 2009.

JA 7607-7608 (emphasis added). The elements of a negligence-based product liability are set forth in *Honaker*, and *Atkinson*, *supra*, and contain no requirement to demonstrate the existence of a safer, alternative design that would reduce or avoid the risk of injury. Moreover, the negligence section of Mr. Combs' law review article makes no mention whatsoever of such a requirement. *See* 113 W. Va. L. Rev. 417, 451-455.

In the final portion of the Negligence Instruction, the District Court again erroneously imported elements of strict product liability:

ii. Reasonably Safe for Intended Use -- State of the Art

In deciding whether the TVT was reasonably safe for its intended use, you should measure its reasonable safeness in comparison to what a reasonably prudent medical device company's standard should have been in 2009. In deciding this question, you may consider the general state of the art of similar medical devices in 2009. Design standards change over time. A medical device company such as Ethicon is entitled to rely upon the state of the art at the time of Mrs. Shears' surgery in 2009. In determining whether Ethicon used state-of-the-art techniques in the design of the TVT in 2009, you should consider the following:

1. Scientific and technical knowledge available;
2. Customary design methods;
3. Safety standards in the medical device industry and Ethicon's compliance or lack thereof with those safety standards; and

4. Inspecting and testing of other similar products.

If you find by a greater weight of the evidence that the TVT conformed to the state of the art in 2009, then you may find that the TVT was reasonably safe for its intended use.

JA 7608-7609. The sentences emphasized above come directly from Syllabus Points 4 and 5 of *Morningstar, supra*.⁷ These Syllabus Points govern only strict product liability claims: not negligence-based product liability claims.

3. The incorrect statement of the law seriously prejudiced the Shears' negligence-based product liability claim.

In a negligence-based product liability claim under West Virginia law, a plaintiff need only prove that the defendant failed to use the amount of care in designing the subject product that a reasonably careful manufacturer would use in similar circumstances to avoid exposing others to a foreseeable risk of harm. *See Honaker*, and *Atkinson, supra*. Despite the fact that West Virginia law makes clear that negligence-based product liability and strict product liability are distinct claims

⁷ “In this jurisdiction the general test for establishing **strict liability in tort** is whether the involved product is defective in the sense that it **is not reasonably safe for its intended use**. The standard of reasonable safeness is determined not by the particular manufacturer, but by what a reasonably prudent manufacturer's standards should have been at the time the product was made.” Syl. Pt. 4, *Morningstar*, 162 W. Va. 857, 253 S.E.2d 666 (1979) (emphasis added).

“The term ‘unsafe’ imparts a standard that the product is to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, **having in mind the general state of the art of the manufacturing process**, including design, labels and warnings, as it relates to economic costs, at the time the product was made.” *Id.* at Syl. Pt. 5 (emphasis added).

with distinct elements, the Negligence Jury Instruction required the Shears to prove all of the essential elements of a strict product liability claim to prevail on their negligence-based product liability claim.

The Shears put on sufficient evidence at trial for a reasonable juror to conclude that Ethicon was negligent in designing the TVT. Specifically, the Shears offered the following evidence:

Due to the serious prejudice resulting from the erroneous Negligence Instruction, the Shears respectfully request that the Court vacate the jury's verdict and order a new trial with a proper negligence-based jury instruction.

VI. CONCLUSION

The Supreme Court of Appeals of West Virginia announces new points of law through syllabus points, concurred in by a majority of the Justices. There are no syllabus points requiring a plaintiff to prove the existence of a feasible, alternative design that would eliminate the risk of injury in order to prevail on a strict product liability design defect claim. The Supreme Court of Appeals of West Virginia adopts rules through administrative orders. There are no administrative orders either adopting or endorsing the WVPJIs. Thus, the WVPJIs are not a pronouncement of West Virginia law. Moreover, proof of a feasible, alternative design conflicts with numerous points of controlling West Virginia law. Under West Virginia law, the Shears were required to present evidence that the TVT was not reasonably safe for

its intended use. The record contains numerous genuine issues of material fact on the issue of the safeness of the TVT. Therefore, the Shears respectfully request that this Court reverse the District Court's grant of summary judgment to Ethicon on the Shears' strict product liability design defect claim.

Similarly, the Shears submitted sufficient evidence for a reasonable juror to conclude that Ethicon's mesh malfunctioned and that said malfunction would not ordinarily happen in the absence of a defect. Accordingly, the Shears respectfully request that this Court reverse the District Court's grant of judgment as a matter of law to Ethicon on the Shears' strict product liability defect claim based on the Malfunction Theory.

Lastly, the District Court erroneously combined elements of both strict product liability and negligence-based product liability in crafting the Negligence Instruction. As a result, the Negligence Instruction was an incorrect statement of West Virginia law. The erroneous instruction significantly increased the Shears' burden of proving a simple negligence claim thereby seriously prejudicing said claim. Therefore, the Shears respectfully request that the Court vacate the jury's verdict and order a new trial with a proper negligence-based jury instruction.

VII. STATEMENT REGARDING ORAL ARGUMENT

Counsel requests oral argument in this case. This appeal raises important issues regarding the correct legal standards governing products liability claims in West Virginia.

Dated: July 1, 2022

Respectfully submitted,

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GARY SHEARS, JR.,**

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Dated: July 1, 2022

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ADDENDUM

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W.VA. P.J.I. §400 PRODUCT LIABILITY — STRICT LIABILITY

§ 411. Design Defect—Necessity of an Alternative, Feasible Design

There are many designs which, although they may eliminate a particular risk, are not practicable to produce. To prove that a design is defective, *[name of plaintiff]* must prove that there was an alternative, feasible design that eliminated the risk that injured *[him/her]*.

Notes and Sources

In Syl. Pt. 4 of *Morningstar v. Black & Decker*, 162 W.Va. 857, 253 S.E.2d 666 (1979), the Court stated:

In this jurisdiction the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use. The standard of reasonable safeness is determined not by the particular manufacturer, but by what a reasonably prudent manufacturer's standards should have been at the time the product was made.

See also, Church v. Wesson, 182 W.Va. 37, 40, 385 S.E.2d 393, 396 (1989) which relies upon Syl. Pt. 4 of *Morningstar* to uphold a directed verdict for defendant, in a strict liability context, on the ground that the plaintiff had failed to establish feasibility of a proffered alternative design.

Following the publication of these pattern instructions, both the Southern District of West Virginia and the Fourth Circuit Court of Appeals have held that West Virginia law requires proof of an alternative, feasible design that eliminates the risk of the alleged injury as an element of plaintiff's product liability claim.

In *Mullins v. Ethicon*, No. 2:12-cv-02952, 2016 WL 7197441 (S.D. W.Va. Dec. 9, 2016), Judge Joseph Goodwin addressed the issue in the context of a medical device case. Specifically, the court considered whether West Virginia law required the plaintiffs to prove that there was a feasible alternative design that would have eliminated the injuries alleged by the plaintiffs, which included erosion, chronic pelvic pain, and dyspareunia. Relying upon *Morningstar*, *Church*, and PJI §§ 409-411, Judge Goodwin held that “in a West Virginia strict liability design defect products liability case, a plaintiff must prove that there was an alternative, feasible design – existing at the time of the product's manufacture – that would have eliminated the *risk* that injured the plaintiff.” *Id.* At *5 (emphasis in original).

Similarly, in *Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. 2017), the Fourth Circuit reversed the district court's decision based on the improper admission of expert testimony under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). As

W.VA. P.J.I. §400 PRODUCT LIABILITY — STRICT LIABILITY

part of its *Daubert* analysis, the Fourth Circuit was required to address the issue of whether West Virginia law required proof of a feasible alternative design. The Court concluded that *Morningstar* requires such proof, holding: “Although *Morningstar* does not use the phrase ‘alternative design,’ a plaintiff in a design case, for all practical purposes, must identify an alternative design in order to establish the ‘state of the art.’” See *Nease*, supra, (relying on *Church* and the Restatement (Third) of Torts: Products Liability § 2, Reporter’s Note (1998)).

W.VA. P.J.I. §400 PRODUCT LIABILITY — NEGLIGENCE

§ 425. Basic Standard of Care

Negligence is the failure to use reasonable care. A [*manufacturer/distributor/seller*] is negligent if [*he/she/it*] fails to use the amount of care in [*designing/manufacturing/warning about*] the product that a reasonably careful [*manufacturer/distributor/seller*] would use in similar circumstances to avoid exposing others to a foreseeable risk of harm.

In determining whether [*name of defendant*] used reasonable care, you should balance what [*name of defendant*] knew or should have known about the likelihood and seriousness of potential harm from the product against the burden of taking safety measures to reduce or avoid the harm.

Notes and Sources

Strahin v. Cleavenger, 216 W.Va. 175, 183, 603 S.E.2d 197, 205 (2004).

Honaker v. Mahon, 210 W.Va. 53, 58, 552 S.E.2d 788, 793 (2001).